

REMARKS/ARGUMENTS

These amendments and remarks are being filed in response to the Office Action mailed April 11, 2007. In that Office Action, Claims 22-25, 27, 28, and 32 were rejected under 35 U.S.C. § 102(e) as being anticipated by Chao (US Patent No. 6,869,438). Claims 22, 25, 26, and 28-32 were rejected under 35 U.S.C. 102(b) as being anticipated by Hopkins (US Patent No. 4,458,681). Claims 22, 25, 27, 28, 32-35, 41 and 43 were rejected under 35 U.S.C. 102(b) as being anticipated by Ersek (US Patent No. 4,378,802). Claims 22, 25, 26, 30-33, 35-41, and 43 were rejected under 35 USC 102(e) as being anticipated by Rennich (US Patent No. 6,960,218). Claims 22, 25, 27, 28, 32-34, 41, and 43 were rejected under 35 USC 102(b) as being anticipated by Caserta (US Patent No. 2,659,378).

A brief review of Applicant's invention may be helpful prior to discussing the relevant references. Applicant's invention is directed to an obesity device that is positioned adjacent to the trachea side of the upper quadrant of a human stomach, with a front side member and a backside member forming a substantially continuous clamping of the stomach so as to form a canal within the stomach that is an extension of the esophageal canal to limit the rate of flow of ingested material into the stomach and to limit the digestion and absorption of the ingested material. As such, the invention relies on the external clamping effect and does not have piercing projections and avoids the severe and irreversible damage to the stomach that results from prior surgical procedures such as vertical banded gastroplasty. The external clamping of the stomach, however, creates some specific challenges. The stomach is bound by tissues to surrounding body structures, and the abdominal cavity is in general a very closed-in space. The positioning and securing of such an external clamp is accordingly difficult.

Applicant's invention addresses the afore-mentioned problems by providing a device in which a front side member is detachably engaged to a connector and, through the connector, to the backside member. The backside member can be placed into position without the front side member in the way. This minimizes the disruption to surrounding tissues. The connector has a receiving portion that is angularly moveable and detachably engages the front side member. The front side member can be attached after the backside member is placed into position behind the stomach. Further, the receiving portion of the connector is angularly movable, which permits the ready attachment of the front side member to the connector from a number of different angles, thereby further facilitating the installation process. Also, the connector has a clamp adjusting mechanism for adjusting the distance between the front side member from the backside member. This allows the positioning of the device while in a wide or "loose" configuration, and then adjustment of the clamping mechanism to clamp the stomach to the degree desired. The adjustable clamping structure further permits the device to be readily removed, or to have the clamping strength adjusted after installation.

Chao (US Patent No. 6,869,438) describes a gastric partition clip that has a one-piece folding clip body with an arched convex portion defining an outlet when the clip has been clamped to the stomach. The Chao clip transverses essentially the entire width of the stomach area that it compresses, and provides only a middle "tunnel" area (the arched convex portion) which permits food to pass from the upper part of the closed-off stomach to the other (see depiction below). The Chao clip does not have an adjustable clamping mechanism, or a detachable front side member to facilitate placement of the device and the making of adjustments and removal of the device after installation. Further, Applicant's invention has substantially

planar front side and backside portions, which thereby do not include the arched convex portions of Chao. Also, sutures 40 are required to maintain the position of the clip, and the need for such is alleviated by the adjustable clamping mechanism.

Hopkins (US Patent No. 4,458,681) discloses a stomach clamp and method for gastric partitioning in which opposed arm ends of a clamp are secured by threaded bolts at lateral ends of the arms, and multiple sutures (Hopkins, Col. 2, l. 24-28). A cylindrical drain 18 is defined by transverse half-cylindrical passages 16 and 17 to permit food to flow through the partitioned stomach. There is no adjustable clamping mechanism, and no angularly movable receiving portion to facilitate placement, adjustment, and removal of the device.

Ersek (US Patent No. 4,378,802), Rennich (US Patent No. 6,960,218), and Caserta (US Patent No. 2,659,378) do not cure the above-noted deficiencies of the prior art. These references are all in the nature of fixed clamps which do not permit adjustment of the spacing between front side and backside portions, and do not have angularly adjustable receiving portions for receiving a detachable front side member.

Applicant submits that the invention is distinct from either of the cited references, and offers distinct advantages. None of the cited references creates a canal within the stomach that is essentially an extension of the esophageal canal, that facilitates placement, adjustment, and removal of the device, and avoids radical surgery to the stomach. Applicant requests reconsideration and allowance of the pending claims.

No fee is believed to be due; however, the Commissioner is hereby authorized to charge any underpayment to Deposit Account No. 50-0951.

Respectfully submitted,

AKERMAN SENTERFITT

A handwritten signature in black ink, appearing to read 'Gregory A. Nelson', is written over a horizontal line.

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